K013387

X. 510 (k) Summary

SUBMITTER: DePuy AcroMed™, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Karen F. Jurczak

DATE PREPARED: October 10, 2001

CLASSIFICATION NAME: Implant, Fixation Device
Spinal Intervertebral Body Fixation Orthosis Device

PROPRIETARY NAME: Stackable Cage System

PREDICATE DEVICES: Stackable Cage System (K001340)

INTENDED USE: The Stackable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Stackable Cage System is also indicated for treating fractures of the thoracic and lumbar spine.

The Stackable Cage System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The Stackable Cage System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Stackable Cage System include DePuy AcroMed titanium plate or rod systems (i.e., Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, Monarch, Profile).

MATERIALS: Carbon-fiber reinforced polymer and titanium alloy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Mr. Frank Maas
Director, Regulatory Affairs
DePuy Acromed
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K013382
Trade Name: Stackable Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Vertebral Body Replacement Device
Regulatory Class: II
Product Code: MQP
Dated: October 10, 2001
Received: October 12, 2001

Dear Mr. Maas:

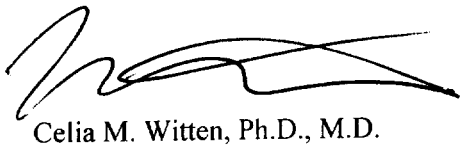
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 0 7 2001

510(k) Number (if known): K013382

Device Name: Stackable Cage System

Indications For Use:

The Stackable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 – L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013382